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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/536,939	04/11/2006	Christophe Revirron	05-403	8331

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MCDONNELL BOEHNEN HULBERT & BERGHOFF LLP  
300 S. WACKER DRIVE  
32ND FLOOR  
CHICAGO, IL 60606

EXAMINER
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RAMACHANDRAN, UMAMAHESWARI

ART UNIT	PAPER NUMBER
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1617

MAIL DATE	DELIVERY MODE
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06/20/2007

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/536,939	<b>Applicant(s)</b> REVIRON, CHRISTOPHE	
	<b>Examiner</b> Umamaheswari Ramachandran	<b>Art Unit</b> 1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 16 May 2007.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 10 and 22-29 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 10 and 22-29 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                  | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### **DETAILED ACTION**

The examiner notes the receipt of the affidavits, remarks and amendments received in the office on 5/16/2007 amending claim 10 and adding claims 22-29. Claims 1-9, 11-21 have been canceled. Claims 10, 22-29 are currently pending.

The rejection of claims 10-21 under 35 U.S.C 112 (1), under 35 U.S.C 102 (b) is rendered moot by the amendment of claim 10 and by the cancellation of claims 11-21. The rejection of claims 11-12, 14-15, 17, 18 and 20-21 anticipated by Gray (WO 94/06429) is rendered moot by the cancellation of claims 11-21. Applicant's response to the rejection of claims 10 and 16 rejected under 35 U.S.C. 103(a) as being unpatentable over Gensthaler (Pharmazeutische Zeitung, vol. 146, no. 7, 2001-02-15, p 35-36) in view of Leynadier et al (Acta Otorhinolaryngol Belg. 2001, 55(4):305-12) is considered but not persuasive. Due to the amendment of claim 10, cancellation of claim 16 and addition of new claims (22-29) a modified 103(a) rejection is made. Also, upon further search and consideration new rejection has been made and is given below. The office action is made non-final.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 10, 22, 23, 25-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gensthaler (Pharmazeutische Zeitung, vol. 146, no. 7, 2001-02-15, p 35-36) in view of Leynadier et al (Acta Otorhinolaryngol Belg. 2001, 55(4): 305-12).

Gensthaler teaches that Levocetirizine was effective in the treatment of patients with seasonal allergic rhinitis (p 35, para 4 lines 1-2). The reference further teaches an intended study of the long-term effect of Levocetirizine in 500 adults with persistent allergic rhinitis (p 36, lines 3-8).

The reference does not teach a method of administration in a daily dosage of about 0.0005 mg to about 2 mg per kg of body weight in treating persistent allergic rhinitis patients or the number of dosages in the intended study of persistent allergic rhinitis.

Leynadier et al teaches a dosage of 2.5, 5, 10 mg/day of levocetirizine by oral administration in a method of treatment for seasonal allergic rhinitis with symptoms such as sneezing, rhinorrhea, nasal congestion, nasal pruritus, ocular pruritus, itchy nose and itchy eyes. For example, administration of 2.5, 5 and 10 mg of Levocetirizine to a 20 kg patient would amount to 0.125 mg/kg, 0.25 mg/kg, and 0.5 mg/kg of body weight, which falls within the range claimed in claims 21 and 22.

It would have been obvious to one of ordinary skill in the art to administer levocetirizine in the treatment of persistent allergic rhinitis because Gensthaler teaches the effectiveness of the compound in seasonal allergic rhinitis and further teaches the intended clinical study of persistent allergic rhinitis with the same compound. Hence one of ordinary skill in the art would have been motivated to administer levocetirizine in the

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treatment of persistent allergic rhinitis to obtain similar therapeutic benefits. It would have been obvious to one of ordinary skill in the art at the time of the claimed invention to administer a dose of 0.0005 mg to about 2 mg per kg of body weight per patient for the treatment of persistent allergic rhinitis. Leynadier et al. teaches range of dosages of levocetirizine administered to subjects suffering from rhinitis. One of ordinary skill in the art would have been motivated to adjust the dosage amount or dosages administered per day by routine experimentation as one can expect similar therapeutic benefits and safety in the administration of levocetirizine to patients with persistent allergy as Leynadier has shown the drug to be safe and therapeutically beneficial in the patients with seasonal allergy rhinitis.

Claims 10, 22-29 are rejected under 35 U.S.C. 103(a) as being Salmun et al. (US 2003/0236275).

Salmun et al. teaches antihistamines such as levocetirizine, desloratadine are useful in the treatment of seasonal allergic rhinitis. The reference teach desloratadine has the added benefit of providing significant relief from persistent allergic symptoms such as nasal congestion/stuffiness in patients with seasonal allergic rhinitis (p 4, para 0050). The reference further teaches a dosage of 2.5 mg to about 45 mg/day of desloratadine in the treatment of allergic and inflammatory conditions (p 2, para 0026) will fall in the range of 0.05 mg/kg to 0.9-mg/kg body weight when administered to a patient weighing 50 kg. The reference also teaches different modes of administration such as topical, inhalation, oral etc. (p 3, para 0037).

The reference does not explicitly teach levocetirizine or desloratadine in the treatment of persistent allergic rhinitis or multiple dosage administration of levocetirizine or the period of administration to be 3 months or more.

It would have been obvious to one of ordinary skill in the art at the time of the invention to administer levocetirizine in a method of treatment for persistent allergic rhinitis because of the teachings of Salmun et al. The reference teaches desloratadine, an antihistamine has the added benefit of providing significant relief from persistent allergy symptoms such as nasal congestion/stuffiness in patients with SAR. It would have been obvious to one of ordinary skill in the art at the time of the invention to administer an antihistamine such as desloratadine or levocetirizine in a method of treatment for persistent allergic rhinitis as Salmun et al. teaches that the antihistamine compound provide significant relief of persistent allergy symptoms such as nasal congestion/stuffiness. Hence one of ordinary skill in the art would have been motivated to achieve similar or superior therapeutic benefits by the administration of levocetirizine to persistent allergy patients. One of ordinary skill in the art at the time of the invention would have been motivated to optimize the parameters such as multiple dosage administration of levocetirizine or period of administration for 3 or more months by routine experimentation as Salmun et al have taught the administration of levocetirizine to be safe and beneficial in rhinitis patients.

### ***Response to Arguments***

Applicants' argue that Leynadier or Gensthaler does not teach dosage or routes of administration effective for the treatment of persistent allergic rhinitis. In response,

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reference teaches the same compound levocetirizine as claimed in the instant application and the dosages in the treatment of seasonal allergy rhinitis. Though the allergies are seasonal and persistent are distinct in nature as pointed out by the Applicants' they belong to the same class (allergies) and hence one of ordinary skill in the art would have been motivated to have a reasonable expectation of success by administering the same dosages or varying the amount of dosages (using Leynadier's teachings as a reference) by routine optimization. It would have been customary for an artisan of ordinary skill to determine the optimal amount of ingredient to add in order to best achieve the desired results. Though Gensthaler does not provide an enabling disclosure the teachings provide motivation to one of ordinary skill in the art to administer levocetirizine in the treatment of persistent allergic rhinitis as Gensthaler teaches the effectiveness of the compound in seasonal allergic rhinitis and further teaches the intended clinical study of persistent allergic rhinitis with the same compound.

### ***Conclusion***

No claims are allowed.

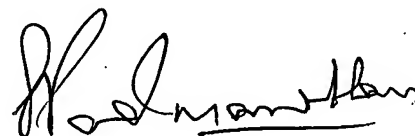
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Umamaheswari Ramachandran whose telephone number is 571-272-9926. The examiner can normally be reached on M-F 8:30 AM - 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on 571-272-0629. The fax phone

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number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



SREENI PADMANABHAN  
SUPERVISORY PATENT EXAMINER